K110356

JUN 10 2011

510(k) Summary

Astra Tech Inc.
Atlantis™ Crown Abutment in Zirconia

ADMINISTRATIVE INFORMATION

510K Preparation Date:	January 4, 2011
Manufacturer Name:	Astra Tech Inc. 590 Lincoln Street Waltham, Massachusetts 02541 Telephone: 781-810-6462 Fax: 781-810-6719
Official Contact:	Franklin Uyleman
Representative/Consultant:	Betsy A. Brown B.A. Brown and Associates Inc. Telephone: 847-560-4406 Fax: 847-677-0177

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Atlantis™ Crown Abutment
Common Name:	Endosseous dental implant abutment 21 CFR 872.3630
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

The Atlantis Crown Abutment in Zirconia is intended for use with an endosseus implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.

INTENDED USE (continued)

This device is compatible with the following manufacturers' implant systems:

Astra – Microthread ST 3.5mm, 4.0mm, 4.5mm and 5.0mm

Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.

Highly angled abutments on small diameter implants are intended for the anterior region of the mouth only.

DEVICE DESCRIPTION

The device covered in this submission is a single restorative component for dental implants that integrates all aspects of the coping and abutment functionalities. The device has a crown shape exterior which allows the porcelain to be applied directly to the surface of the screw retained abutment and provides support for the described prosthetic restoration. The **Atlantis Crown Abutment in Zirconia** design is different than an Atlantis Abutment for cement-retained restoration in that the basis for its individualized design is the final crown.

Please see Figure #1 and Figure #2 for additional detail:

Figure #1:

Atlantis abutment for cement-retained restorations - The abutment shown in green (crown is shown for completeness in yellow) is intended to simulate the geometry of a prepped tooth. It has a core axis which may be different than the implant axis. The difference in these axes is referred to as angular correction. In addition, the design of this abutment takes into consideration the "path of insertion" of the coping and provides the necessary taper geometry and retention aspects to accommodate this separate component.

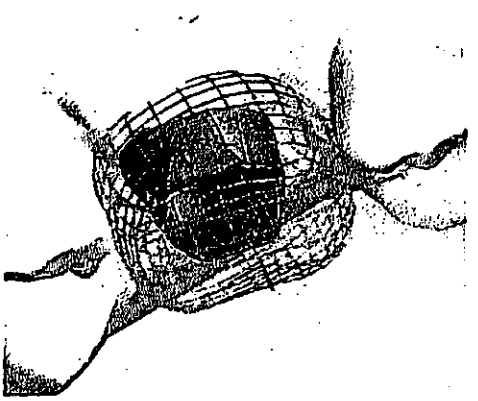
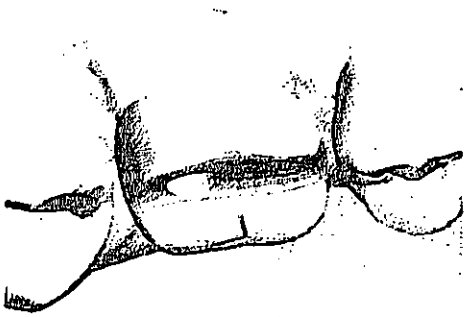


Figure #2:

Atlantis crown abutment in zirconia for screw-retained restorations -The abutment shown in the illustration has a shape that is closer to the final geometry of the crown. The intent of the design is not to provide full anatomical features of a finished crown but to provide just enough structure to fill the edentulous space and to provide an appropriate substructure to support porcelain. As such, the basis of an Atlantis crown abutment in zirconia design is the final crown minus the desired porcelain thickness the customer intends to apply. An Atlantis crown abutment in zirconia does not have a "correction angle" relative to the implant axis or a coping "path of insertion" as described for conventional cement retained abutments.



The subject crown abutment is indicated for screw retained restorations. The **Atlantis™ Crown Abutment in Zirconia** is made of biocompatible material, yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) and meets ISO Standards 6972 & 13356. Zirconia may have variation in shade. The **abutment screw** is made of Titanium grade Ti-6A1-4V ELI and complies with ASTM Standard F-136. The zirconia screw retained abutments are placed over the implant shoulder and are mounted into the implant with the titanium screw.

EQUIVALENCE TO MARKETED DEVICE

Astra Tech Inc. demonstrated that, for purposes of the FDA's regulations of medical devices, the **Atlantis™ Crown Abutment in Zirconia** is substantially equivalent in indications and design principles to the Atlantis™ Abutment for Astra Implants cleared under K071946 which has been determined by FDA to be substantially equivalent to preamendment devices.

Table 1: Substantial Equivalence Summary

Technological Characteristics	**Atlantis™ Crown Abutment in Zirconia**	**Atlantis™ Abutment for Astra Implants (K071946)**
Material	-Titanium Alloy (screw) -Biocompatible ceramic material (abutment)	-Titanium Alloy (screw) -Biocompatible ceramic material (abutment)
Performance characteristics	Allows the prosthesis to be screw retained to the endosseous implant.	Allows the prosthesis to be cemented or screw retained to abutment. While the abutment screw is intended to secure the abutment to the endosseous implant.
Intended Use	The Atlantis crown abutment in zorconia is intended for use with an endosseus implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant	Intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. Intended for use to support single or multiple tooth prosthesis, in mandible or maxilla.

Summary of Non-clinical Testing

Static and fatigue compression testing was conducted on "worst case scenario" implant assemblies for the Atlantis angled zirconia crown abutments with the Astra implant. Test results demonstrate that the Atlantis Crown Abutment is compatible with the Astra implants and the implant system supported appropriate static and fatigue test loads demonstrating that the implant system performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 10 2011

Astra Tech, Incorporated
C/ O Ms. Betsy A. Brown
Regulatory Consultant
B.A. Brown & Associates
8944 Tamaroa Terrace
Skokie, Illinois 60076

Re: K110356
Trade/Device Name: Atlantis™ Crown Abutment in Zirconia
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 27, 2011
Received: June 1, 2011

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K110356

Device Name: Atlantis™ Crown Abutmen in Zirconia

Indication for Use:

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Prescription Use___X____ (Part 21 CFR 801 Subpart D)

AND/OR Over-the-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110356